

10/13/05

See attached form for additional information.

11/11/05

Interagency Report Control No.:

A 4/07/05

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 43-R-0114  
CUSTOMER NUMBER: 1823

FORM APPROVED  
OMB NO. 0579-0036

J.E. Shuster

ANNUAL REPORT OF RESEARCH FACILITY  
(TYPE OR PRINT)

Quintiles, Inc.  
10245 Hickman Mills Dr  
Kansas City, MO 64137

Telephone: (816)-767-6000

COPY FOR YOUR INFORMATION

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS  (COLUMNS C + D + E)
4. Dogs	15	96	174	2	272
5. Cats					
6. Guinea Pigs					
7. Hamsters					
8. Rabbits	0	0	29	0	29
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and apr Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary in brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGNATURE OF C.E.O.

(b)(6), (b)(7)(C)

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

(b)(6), (b)(7)(C)

DATE SIGNED

26 Oct 2005

APHIS FORM 7023

(AUG 91)

(replaces VET FORM 10-23 (OCT 88), which is obsolete.)

OCT 28 2005

INFORMATION

### Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. **Registration Number:** 43-R-0114
2. **Number of animals used in this study:** 2
3. **Species (common name) of animals used in the study:** Dogs
4. **Explain the procedure producing pain and/or distress.**

Dog #1 was purchased to support an IACUC approved standard Pharmacokinetic studies with no anticipated pain or distress; administration of a test compound and periodic blood collections after dosing. The dog was received by the vendor with abnormal blood work. The veterinary care staff did not release the dog for the study. The dog was found dead in its cage upon AM observation. Our current policy is to assume and assign the animal to the worst-case pain category.

Dog #2 was designated to support an IACUC approved standard Pharmacokinetic studies with no anticipated pain or distress; administration of a test compound and periodic blood collections after dosing. The dose route was oral, to be administered via gavage (stomach tube). Misdosing occurred and a small amount of the test article was administered into the lungs rather than the stomach resulting in difficult breathing and lethargy.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For federally mandated testing, see Item 6 below).**

Pain and/or distress was relieved with intravenous administration of an euthanasia solution to Dog #2 when determined to be moribund.

6. **What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific number (e.g., APHIS, 9 CFR 113.103):**

Agency N/A CFR N/A

OCT 28 2005